DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Buckeye Medical Technologies LLC
Terry Philibin, DDS, MS, MBA
President/CEO
405 Niles Cortland Road SE, Suite 202
Warren, Ohio 44484

September 28, 2017

Re: K171922
Trade/Device Name: Anatotemp Anatomic Dental Implant Healing Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: August 31, 2017
Received: September 1, 2017

Dear Terry Philibin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mary S. Runner -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171922

Device Name

Anatotemp Anatomic Dental Implant Healing Abutment

Indications for Use *(Describe)*

The Anatotemp Anatomic Dental Implant Healing Abutment is a pre-manufactured healing abutment intended for use with endosseous root-form dental implants to aid in prosthetic rehabilitation. The abutment is a temporary device that aids in creating an esthetic emergence through the gingiva during the healing period. The single use, sterilized device is used by dental professionals during the dental implant healing process and is removed prior to permanent prosthetic placement.

Anatotemp Anatomic Dental Implant Healing Abutments are compatible with the following implant systems:

Implant Brand and Type	Implant Platform Size
Implant Direct Legacy	3.5mmD, 4.5mmD, 5.7mmD
Implant Direct ReActive	3.5mmD, 4.3mmD, 5.0mmD
Implant Direct RePlus	3.5mmD, 4.3mmD, 5.0mmD
Implant Direct RePlant	3.5mmD, 4.3mmD, 5.0mmD, 6.0mmD
Implant Direct SwishPlus	4.8mmD, 6.5mmD
Implant Direct InterActive	3.0mmD, 3.4mmD
Implant Direct SwishActive	3.0mmD, 3.4mmD
Blue Sky Bio Quattro	Regular Platform (RP)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K171922

510(k) Summary

Summary of information in accordance with SMDA 1990 and CFR 807.92

I. SUBMITTER

Buckeye Medical Technologies LLC
405 Niles Cortland Rd SE Ste 202
Warren, OH 44484

Phone: (330) 719-9868
Contact: Terry B Philibin DDS, MS, MBA
Email: tphilibin@anatotemp.com
Date Prepared: September 26, 2017

II. DEVICE

Device Trade Name:	Anatotemp Anatomic Dental Implant Healing Abutment
Device Common Name:	Anatomic Dental Implant Healing Abutment
Device Classification Name:	Endosseous Dental Implant Abutment
Regulatory Class:	Class II
Regulation Number:	21 CFR 872.3630
Product Code:	NHA

III. PREDICATE DEVICE

Predicate:

Contour Healer (K112099)

Reference Predicates:

Legacy Dental Implants (K073033)
ReActive Dental Implant System (K080713)
RePlus Dental Implants (K073161)
Spectra System (K061319)
InterActive/ SwishPlus2 Implant System (K130572)
InterActive/SwishActive System (K143011)
Blue Sky Bio Dental Implant System (K102034)

IV. DEVICE DESCRIPTION

The Anatotemp Anatomic Dental Implant Healing Abutment product line includes anatomically shaped temporary dental implant healing abutments that aid in creating an esthetic emergence through the gingiva during the healing period. Anatotemp Anatomic Dental Implant Healing Abutments are made of a polymethylmethacrylate biocompatible plastic and are held securely to an endosseous implant with a titanium abutment screw. Anatotemp Anatomic Dental Implant Healing Abutments are positioned well below the occlusal plane and are non-load bearing components that guide healing tissue.

Anatotemp Anatomic Dental Implant Healing Abutments are designed not to be in occlusion or sustain occlusal forces. Anatotemp Anatomic Dental Implant Healing Abutments come in six shapes that mimic original tooth shape at the gingival level and also exhibit a mild, biconcave shape interproximally that aids in creating an esthetic emergence through the gingiva during the healing period. Anatotemp Anatomic Dental Implant Healing Abutments exhibit anti-rotational connections that are compatible with many dental implant connections. Anatotemp Anatomic Dental Implant Healing Abutments are provided sterile, are single use, and are recommended for temporary placement of no longer than 180 days. Anatotemp Anatomic Dental Implant Healing Abutments are removed after dental implant healing (approximately 90-180 days) and replaced by the permanent abutment and crown.

V. INDICATIONS FOR USE

The Anatotemp Anatomic Dental Implant Healing Abutment is a pre-manufactured healing abutment intended for use with endosseous root-form dental implants to aid in prosthetic rehabilitation. The abutment is a temporary device that aids in creating an esthetic emergence through the gingiva during the healing period. The single use, sterilized device is used by dental professionals during the dental implant healing process and is removed prior to permanent prosthetic placement.

Anatotemp Anatomic Dental Implant Healing Abutments are compatible with the following implant systems:

Implant Brand and Type	Implant Platform Size
Implant Direct Legacy	3.5mmD, 4.5mmD, 5.7mmD
Implant Direct ReActive	3.5mmD, 4.3mmD, 5.0mmD
Implant Direct RePlus	3.5mmD, 4.3mmD, 5.0mmD
Implant Direct RePlant	3.5mmD, 4.3mmD, 5.0mmD, 6.0mmD
Implant Direct SwishPlus	4.8mmD, 6.5mmD
Implant Direct InterActive	3.0mmD, 3.4mmD
Implant Direct SwishActive	3.0mmD, 3.4mmD
Blue Sky Bio Quattro	Regular Platform (RP)

VI. COMPARISONS OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

Table 1

Parameter	Device	Predicate Device	Differences
Device Name	Anatotemp Anatomic Dental Implant Healing Abutment	Contour Healer	Device Name difference does not affect substantial equivalence (SE)
Company Name	Buckeye Medical Technologies LLC	Contour Healer LLC	Company Name difference does not affect SE
510(k)	K171922	K112099	510(k) # difference does not affect SE
Class	II	II	Same
21 CFR Number	872.3630	872.3630	Same
Code	NHA	NHA	Same
Description	Temporary healing abutment is a plastic component with an anatomic contour at tissue level and an anti-rotational connection feature that engages the internal aspects of the endosseous implant and is secured with a titanium screw. Abutments are straight versions only.	Abutment is a plastic post with a predefined junction and abutment core. The plastic stem of the abutment engages the internal aspects of the endosseous implant and is secured with a separate retaining screw. The abutment is packaged with a stainless steel screw for retaining the temporary healing abutment to the endosseous implant. The abutments are provided in straight versions only.	Descriptions are the same except for the inclusion of a titanium screw with the Device and a stainless steel screw with the Predicate Device. This material selection difference does not affect SE
Use Features	Premanufactured prosthetic dental implant healing abutment. Screw retained.	Pre-manufactured prosthetic component; screw-retained	Same
Ancillary Components	Not applicable. Used temporarily, attached to permanent dental implant during healing phase.	Not applicable; for attachment to endosseous permanent implant	Same
Intended Use	Temporary dental implant healing abutment used in conjunction with permanent endosseous dental implant fixture to aid in prosthetic rehabilitation.	To be used in conjunction with an endosseous dental implant fixture to aid in prosthetic rehabilitation	Same

Indications for Use	The Anatotemp Anatomic Dental Implant Healing Abutment is a pre-manufactured healing abutment intended for use with endosseous root-form dental implants to aid in prosthetic rehabilitation. The abutment is a temporary device that aids in creating an esthetic emergence through the gingiva during the healing period. The single use, sterilized device is used by dental professionals during the dental implant healing process and is removed prior to permanent prosthetic placement. Anatotemp Anatomic Dental Implant Healing Abutments are compatible with the following implant systems: Implant Direct [Legacy] 3.5mmD, 4.5mmD, 5.7mmD Implant Direct [ReActive] 3.5mmD, 4.3mmD, 5.0mmD Implant Direct [RePlus] 3.5mmD, 4.3mmD, 5.0mmD Implant Direct [RePlant] 3.5mmD, 4.3mmD, 5.0mmD, 6.0mmD Implant Direct [SwishPlus] 4.8mmD, 6.5mmD Implant Direct [InterActive] 3.0mmD, 3.4mmD Implant Direct [SwishActive] 3.0mmD, 3.4mmD Blue Sky Bio [Quattro] Regular Platform (RP)	The Contour Healer Temporary Abutment is intended for use with a root-form endosseous dental abutment to aid in prosthetic rehabilitation. The abutment is a provisional restoration that aids in creating an esthetic emergence through the gingiva during the healing period. The device is for use by dental professionals for single restorations in adults. The device is for single-use only and may not be re-processed. These abutments are designed to work with the following implant systems: Zimmer [Screw-Vent Dental Implant System] Nobel Biocare [Replace HA Coated Implant, Replace TiUnite Endosseous Implant, Nobel Biocare Endosseous Implants, and Groovy Implants] BioHorizons [BioHorizons Tapered Internal Implant System]	The Indications for Use differ in compatible implants.
End User	Implant dentist, Oral Surgeon, Periodontist, Prosthodontist	Dentist, periodontist, oral surgeon	Same
Frequency of Use	Single Use	Single Use	Same
Method of Use	Temporary dental implant healing abutment: 180 days maximum.	Temporary prosthesis; 90 days maximum	180 days vs. 90 days maximum implantation time. Additional testing was conducted on the Device to ensure a longer implantation duration; this does not affect SE
Abutment Material	Polymethylmethacrylate (PMMA)	PEEK Classix; polyetheretherketone	PMMA vs. PEEK Classix. Materials are different, but extensive testing shows that both materials are biocompatible; thus, this does not affect SE

Abutment Design	Temporary healing abutment with anatomic shapes to mimic tooth shape at the tissue level and specific tooth locations. Various platform sizes included the following: 3.5, 4.5, 5.7, 3.5, 4.3, 5.0, 6.0, 4.8, 6.5, 3.0, 3.4, and RP. Straight versions only.	Contoured shaped with interfaces to match endosseous implants with various platform size [abutment to implant diameters of 5.0, 4.3, 4.5, and 5.7mm], in straight versions only	Inclusion of additional implant platform diameters does not affect SE
Implant/Abutment Connection	Various shaped abutment connections used to engage the permanent implant and provide anti-rotational stability	Various shaped abutment connections used to engage the permanent implant and provide anti-rotational stability	Same
Screw Material	6AL-4V ELI Titanium	Stainless Steel	Titanium vs. Stainless Steel. Testing of Device screw showed that the screw is biocompatible; thus, this does not affect SE
Sterility	Sterilized via ethylene oxide	Non-sterile; intended for autoclave sterilization by end user	Sterile vs. Non-Sterile. Sterilization of device does not affect SE.
Packaging	Sealed Tyvek PETG single unit trays	Round plastic vial with screw cap	PETG Tray vs. Plastic Vial. PETG packaging does not affect SE.

VII. PERFORMANCE DATA

Non-Clinical Testing

Non-clinical testing included biocompatibility testing of the abutment material and titanium abutment screw, chemical characterization of abutment material, biological risk assessment of the abutment material, packaging validation, sterilization validation, shelf-life validation, and reverse engineering analysis of the OEM implant systems.

Chemical testing for the Anatotemp Anatomic Dental Implant Healing Abutment included:

- Chemical Characterization ISO 10993-18

Biocompatibility testing for the Anatotemp Anatomic Dental Implant Healing Abutment included:

- Cytotoxicity Using the ISO Elution Method ISO 10993-5
- ISO Maximization Sensitization Study ISO 10993-10
- ISO Intracutaneous Study ISO 10993-10
- ISO Systemic Toxicity Study ISO 10993-11
- Bacterial Reverse Mutation Study ISO 10993-3

- Implantation (4 wk rabbit) ISO 10993-6
- Implantation (9 wk rabbit) ISO 10993-6
- ISO Intracutaneous Study w/ EO Cycle 20 ISO 10993-10

Biocompatibility testing for the Titanium Dental Screw included:

- Cytotoxicity Using the ISO Elution Method ISO 10993-5

Chemical characterization testing was performed on the Anatotemp Anatomic Dental Implant Healing Abutment per ISO 10993-18 “Chemical characterization of materials” and United States Pharmacopeia (USP) Physiochemical Tests – Plastics <661>.

A Biological Risk Assessment was generated based upon the results of the biocompatibility tests on the Anatotemp Anatomic Dental Implant Healing Abutment. “Based on the results of the biological and chemical characterization testing, the Anatotemp would not be expected to be toxic, carcinogenic, or cause adverse reactions when in contact with tissue/bone.”

Cytotoxicity testing was also performed for the Titanium Dental Screw per ISO 10993-5, and the testing showed that the “test article extract showed no evidence of causing cell lysis or toxicity.”

The sterilization validation methodology was based on EN ISO 11135:2014 and ISO 11135:2014 requirements. This protocol details a full sterilization process validation using the **overkill half-cycle approach**. Successful completion of the validation process demonstrated that the product can be reliably sterilized to a sterility level of 10^{-6} using the current validated Cycle 20 (EXC-1.)

Packaging validation study was also conducted. According to ATPKG01 Protocol, “the purpose of this validation study is to ensure that the specified packaging will protect the device from damage during the post-sterilization handling and storage while maintaining sterility during the state shelf life,” and the validation study is “based on BS EN ISO 11607-1:2009+A1: 2014 standard titled: *Packaging for Terminally Sterilized Medical Devices – Part 1, sections 6.3.5, 6.4.2, and 6.4.3.”* In the ATPKG01: Distribution Simulation Report Executive Summary, it states that “The distribution simulation study has been completed and has met the stated requirements.”

Thirty-six-month packaging accelerated aging validation was also conducted in accordance with ATPKG01 Rev. A Protocol, *Packaging for Terminally Sterilized Medical Devices: BS EN ISO 11607-1:2009+A1:2014.* The Anatotemp Anatomic Dental Implant Healing Abutment packaging met the stated requirements outlined in protocol ATPKG01 for accelerated aging, visual inspection, dye penetration testing, and peel testing. Accelerated aging was performed according to ASTM F1980-07 (2011).

Reverse engineering analysis testing was conducted on the OEM implant systems with which we claim compatibility. A sample of the OEM implants were measured and analyzed using statistical software to identify tolerance limits for our designs. Additionally, the OEM screws were measured and tested using GO/NO-GO gauges. In order to ensure ongoing implant to proposed device compatibility, the previously described engineering studies will be performed on an annual basis.

Clinical Testing

Formal clinical studies were not conducted to support the claim for substantial equivalence to the predicate device following the recommendations of the Class II Special Control Guidance Document: Root-form Endosseous Dental Implants and Dental Implant Abutments issued May 12, 2004.

VIII. COMPARISON STATEMENT AND CONCLUSIONS

The new device and the predicate device are both non-load bearing temporary anatomic dental implant healing abutments. Both are used during the time of dental implant healing and then removed prior to permanent dental implant abutment and crown placement. Both devices exhibit a tooth shape at the tissue level and exhibit an anti-rotational connection feature that inserts into the dental implant. Both devices are secured with an abutment screw. Both devices are positioned well below the occlusal plane and designed to be non-load bearing. Both devices are not used for occlusal function.

The Anatotemp Anatomic Dental Implant Healing Abutment does differ from the predicate device in material composition. The Anatotemp Anatomic Dental Implant Healing Abutment is fabricated from a polymethylmethacrylate plastic as opposed to polyetheretherketone (PEEK Classix). Due to the device being in contact with tissue for greater than 30 days, an exhaustive risk assessment analysis was undertaken including biocompatibility and chemical characterization studies. This analysis concluded that the Anatotemp Anatomic Dental Implant Healing Abutment would not be expected to be toxic, carcinogenic, or cause adverse reactions when in contact with tissue/bone. Cytotoxicity testing on the titanium abutment screw also returned results which determined that the screws showed no evidence of causing cell lysis or toxicity.

The information provided in this submission demonstrates that the Anatotemp Anatomic Dental Implant Healing Abutment is substantially equivalent to the predicate device.